FDA 510(k) Premarket Notification

K913517 ISOLATE INFUSION CATHETR SYSTEM

CLEARED

Nov 5, 1991
90 days to decision

K913517 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k913517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 7, 1991
Decision date	Nov 5, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lake Region Mfg., Inc.**
Location	Mchenry, IL, US
Contact	PAUL KOHL
510(k) history	42 submissions · 42 cleared · 1977-2010